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08/737,319	11/12/1996	SUSUMU KAJIWARA	081356/011	5074

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[REDACTED] EXAMINER

KERR, KATHLEEN M

[REDACTED] ART UNIT

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1652

DATE MAILED: 04/24/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	08/737,319	KAJIWARA ET AL.
	Examiner Kathleen M Kerr	Art Unit 1652

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 March 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 6-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 7 and 8 is/are allowed.
- 6) Claim(s) 6,9 and 11 is/are rejected.
- 7) Claim(s) 10 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>17</u> . | 6) <input type="checkbox"/> Other: _____ .                                   |

## **DETAILED ACTION**

### *Application Status*

1. The previous Office action was a suspension letter (Paper No. 16, mailed on June 30, 2000). The instant Office action is reopening prosecution to address newly identified issues with the pending claims. Claims 6-11 are pending in the instant Office action and will be examined herein.

### *Priority*

2. The instant application is granted the benefit of priority for the foreign application 51234/1995 filed in Japan on March 10, 1995 as requested in the declaration. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. However, said papers are not in English. While priority is granted, the effective filing date of the pending claims cannot be assessed with respect to the priority document until a certified translation is filed. Thus, for purposes of the instant Office action, the effective filing date of the pending claims is March 8, 1996 (the international filing date).

### *Information Disclosure Statement*

3. The information disclosure statement filed on March 19, 2003 (Paper No. 17) has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy. Also associated with the instant application is an information disclosure statement (Paper No. 5) filed on March 26, 1998; this statement had previously been considered.

*Drawings*

4. The drawings are considered informal for the reasons detailed in the copy of PTO Form 948 attached to Paper No. 9. Appropriate correction is required in response to the instant Office action and may not be held in abeyance (see 37 C.F.R. § 1.85(a)).

*Objections to the Specification*

5. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner suggests the removal of the reference to SEQ ID NOs (since the sequence listing may not be available to everyone with access to the Abstract) and inclusion of the full name of the enzyme, isopentenyl pyrophosphate (IPP) isomerase, and the source species, *Phaffia rhodozyma* and *Haematococcus pluvialis* for completeness.

6. The specification is objected to because the title is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The Examiner suggests the following new title:

---DNA Molecules encoding Isopentenyl Pyrophosphate and Methods of Producing Carotenoids Using the Same---

***Objections to the Claims***

7. Claims 9 and 10 are objected to for improper English. The phrase “carotenoids-producing microorganism” or “carotenoids producing microorganism” must be written as --- carotenoid-producing microorganism--- to properly modify the noun of the phrase.
8. Claim 11 is objected to for a typographical error. The term “pluvialis” is misspelled. The correct spelling is ---pluvialis--- as found throughout the specification as in other claims.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 6, 9, and 11 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 6 is drawn to a DNA molecule encoding IPP isomerase from either *Phaffia rhodozyma* or *Haematococcus pluvialis*. Claim 11 is drawn to a protein that is IPP isomerase from *Haematococcus pluvialis*.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” University of California v. Eli Lilly and

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Co., 1997 U.S. App. LEXIS 18221, at \*23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, a single DNA from each of *Phaffia rhodozyma* and *Haematococcus pluvialis* encoding IPP isomerase is described; a single protein that is IPP isomerase from *Haematococcus pluvialis* is described. These genes or proteins are only described according to the functional characteristics (of the enzymes they encode); no structural relationship is described or used in the instant claims. No description of general *Phaffia rhodozyma* and *Haematococcus pluvialis* genes or proteins is noted. These single examples do not adequately describe the claimed genus because one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure. Therefore, claims drawn to DNA, methods of making carotenoids using said DNA, and the encoded polypeptide are not adequately described.

#### *Summary of Pending Issues*

10. The following is a summary of the issues pending in the instant application:

- a) The drawings are considered informal.
- b) The Abstract stands objected to.

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- c) The title stands objected to.
- d) Claims 9 and 10 stand objected to for improper English.
- e) Claim 11 stands objected to for a typographical error.
- f) Claims 6, 9, and 11 stand rejected under 35 U.S.C. § 112, first paragraph, written description.

***Allowable Subject Matter***

11. Claims 7 and 8 are allowable. The closest art to Claim 7 is a disclosure of SEQ ID NO:1 in USPN 6,329,141 (SEQ ID NO:21) (see PTO Form-892); see in particular, Claim 11. The closest prior art to Claim 8, drawn to a DNA encoding SEQ ID NO:2 (*H. pluvialis*), is the *C. breweri* mRNA sequence taught by Blanc *et al.* (GenBank Accession Number X82627, November, 1994 - see attached PTO-892), which encodes a protein about 40% identical to SEQ ID NO:2. Concerning USPN 5,744,341 to Cunningham *et al.* who teach a sequence almost identical to SEQ ID NO:2, the Examiner notes that the earliest effective filing date is March 29, 1996, which does not qualify under prior art for the instant application whose effective filing date is at least March 8, 1996.

Claim 10 is objected to for a minor informality. Claim 10 is drawn to using a DNA encoding the *Saccharomyces* IPP isomerase to enhance carotenoids in a carotenoid-producing cell. Although this DNA is known in the prior art (see Anderson *et al.* in IDS # 5), the prior art neither teaches nor fairly suggests its transformation into carotenoid-producing microorganisms.

***Conclusion***

12. Claims 7 and 8 are allowed. Claim 10 is objected to. Claims 6, 9, and 11 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to

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the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



KMK

April 21, 2003